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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/005,035	01/09/98	LAW	P 038007/0112

EXAMINER	
BECKERLEG, A.	
ART UNIT	**PAPER NUMBER**
1632	3

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DATE MAILED: 05/07/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

File

Office Action Summary	Application No. 09/005,035	Applicant(s) Peter Law
	Examiner Anne Marie S. Beckerleg	Group Art Unit 1632

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *1* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-19* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-19* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-4, 9-13 and 19, drawn to methods of treating disease and methods of controlling the size, shape, or consistency of body parts using cultured myogenic cells, and cloned cell lines either lacking or mildly expressing MHC-I, classified in class 424 and 435, subclass 93.21 and 325.

II. Claims 5-8, and 17-18 drawn to methods of controlling cell fusion using chondroitin-6-sulfate proteoglycan and methods for producing cardiomyocytes comprising cell fusion, classified in class 435, subclass 383 and 384.

III. Claims 14-15, drawn to an automated cell processor, classified in class 435, subclass 283.1.

IV. Claim 16, drawn to a method for producing a normal child, unclassified.

Invention I is distinct from invention II in that the methods for treating disease of invention I are all practiced *in vivo* and as such require the practice of substantially different techniques which operate according to materially different principles than *in vitro* methods of cell fusion.

Inventions I and II are unrelated to invention III in that an automated cell processor of invention III is made using completely different techniques and materials from those involved in *in*

vivo gene therapy. Further, the methods of invention I do not require the use of the automated cell processor or invention III as they can be cultured by hand.

Inventions I-III are unrelated to invention IV in that the techniques and materials required to generate the chimeric or transgenic human child of invention IV, such as *in vitro* fertilization and blastomere recombination, are substantially different from those used to culture or fuse myogenic cells and treat disease using the myogenic cells of inventions I and II, and are also substantially different from the culture apparatus of invention III.

Furthermore, the inventions have acquired a separate status in the art because of their recognized divergent subject matter and different classification. For this reason, the search required for each invention is distinct from the search required for the others. Therefore, for the reasons given above, restriction for examination purposes as indicated is proper.

Claims 1 is generic to a plurality of disclosed patentably distinct species comprising 1) normal myoblasts, 2) genetically transduced myoblasts, and 3) phenotypically converted myoblasts. The specification discloses that retrovirus transduced myoblasts represent an embodiment of the instant invention. Transduced myoblasts are patentably distinct from normal myoblasts in that they contain heterologous nucleic acid sequences which may affect the structure and function of the myoblasts. The specification further discloses that phenotypically converted myoblasts such as osteoblasts or chondrocytes represent another embodiment of the invention. Phenotypically converted myoblasts are patentably distinct from myoblasts in that osteoblasts and chondrocytes are differentiated cells which develop from myoblasts, and as such have substantially

different chemical and structural properties than their more primitive ancestors. For these reasons, normal myoblasts, transduced myoblasts, and phenotypically converted myoblasts are patentably distinct species. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Beckerleg, Ph.D., whose telephone number is (703) 306-9156. The examiner can be reached Mon-Thurs and every other Friday from 8:30-6:00. General inquiries should be directed to the group receptionist whose phone number is (703) 308-0196. The official fax number is (703) 308-4242.

Deborah Crouch

DEBORAH CROUCH
PRIMARY EXAMINER
GROUP 1800/1630

Dr. A.M.S. Beckerleg

4/26/99